



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,754	02/19/2002	Matthew Glenn	11000.1068	9113
20601	7590	01/22/2004	EXAMINER	
SPECKMAN LAW GROUP 1501 WESTERN AVE SUITE 100 SEATTLE, WA 98101			MARTINELL, JAMES	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/079,754	Applicant(s) GLENN ET AL.	
	Examiner James Martinell	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9,10 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 5,9,10 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

Art Unit: 1631

Claims 1-4 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed November 10, 2003.

The disclosure is objected to because of the following informalities.

- (a) The passage in the specification at page 2, lines 29-30, "(e) sequences having a 99% probability of being to the same as a sequence of (a)-(d)" does not make sense.
- (b) The status of each of the parent applications should be updated.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptide SEQ ID NO: 10 encoded by SEQ ID NO: 4, does not reasonably provide enablement for all other polypeptide sequences encoded by SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. SEQ ID NO: 4 encodes polypeptides other than the polypeptide that is SEQ ID NO: 10 (*e.g.*, there are five reading frames other than the reading frame that encodes SEQ ID NO: 10). The instant application does not teach one of skill in the art how to make and use polypeptides encoded by reading frames in SEQ ID NO: 4 other than the reading frame that encodes SEQ ID NO: 10.

Claims 9, 10, 18, and 20 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sequences that are specifically disclosed, does not reasonably provide

Art Unit: 1631

enablement for sequences that are 75%, 90%, or 95% identical to SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant application provides no guidance for one of skill in the art to make and use active variants of SEQ ID NO: 10 that are embraced by the claims. It would require undue experimentation for one of skill in the art to arrive at active variants of SEQ ID NO: 10 because of the large number of embodiments embraced by the claims (*e.g.*, there are no fewer than  $2.17 \times 10^{31}$  75% identical sequences to SEQ ID NO: 10,  $2.88 \times 10^{15}$  90% identical sequences to SEQ ID NO: 10, and  $6.84 \times 10^5$  identical sequences to SEQ ID NO: 10) and the lack of guidance for one of skill in the art in choosing which of the large number of sequences to produce and test for histatin activity.

Claims 9, 10, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) The recitation of "comprising at least a functional portion of SEQ ID NO: 10" (claim 19) is vague and indefinite because the instant application does not identify with particularity, the functional portion of SEQ ID NO: 10.
- (b) The recitation of "comprising at least a functional portion . . . wherein the polypeptide has substantially the same functional activity as SEQ ID NO: 10" (claim 20) is vague and indefinite because the instant application does not identify with particularity, the functional portion of SEQ ID NO: 10 or the variants to SEQ ID NO: 10 that are 75%, 90%, or 95% identical to SEQ ID NO: 10.

Claim 17 is allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-

Art Unit: 1631

mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

**PLEASE NOTE THE NEW FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.  
Primary Examiner  
Art Unit 1631**